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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,289	10/25/1999	John Luke Toner	NIDN-72124	9341
36335	7590	11/01/2004	EXAMINER	
AMERSHAM HEALTH IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231			HARTLEY, MICHAEL G	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/425,289

Applicant(s)

TONER ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

The amendment filed 8/26/2004 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38 and 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the office action mailed 4/21/2004.

Response to Arguments

Applicant's arguments filed 8/26/2004 have been fully considered but they are not persuasive.

Applicant asserts that the claim is clear because it states "embolus generating composition" and further comprising various contrast agents.

This is not found persuasive because it is not the embolus generating composition which was stated as being confusing. Rather it is the recitation of "diagnostically effective compound" earlier in the claim and "further comprising further comprises an iodinated contrast agent, MRI active agent or ultrasound contrast agent" and it is unclear if the recitation of the contrast agents is further defining the diagnostically effective compound or is in addition thereto (which is usually provided by the recitation of "further comprising" as claimed).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 4-6 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuru (US Pat. 5,055,307), for the reasons set forth in the office action mailed 4/21/2004.

Claims 38 and 4-6 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Unger (US 5,585,112), for the reasons set forth in the office action mailed 4/21/2004.

Response to Arguments

Applicant's arguments filed 8/26/2004 have been considered but are not found persuasive.

Applicant asserts that Tsuru fails to disclose methods that use solid water-soluble particles encapsulated by a non-polymeric matrix.

This argument is not seen relevant, as this is not in line with the claim language. In the claims the particles are not encapsulated by the matrix, but the matrix makes up the particles, which encapsulate the non-radioactive diagnostically effective compound.

Applicant asserts that Tsuru does not disclose the particles as claimed having a non-radioactive compound encapsulated in a non-polymeric matrix.

This is not found persuasive because the particles are the same as claimed, hydroxyapatite, which encapsulate an diagnostically effective compound, such as, an X-ray contrast agent, as well as, calcium phosphate, which would be within the broad scope of "a non-radioactive diagnostically effective" compound, as such a metal would enhance MRI, as well as, X-ray. Tsuru discloses the same composition as defined and exemplified by the instant specification. Example 1 of Tsuru discloses a water soluble hydroxyapatite porous particle which encapsulates a iodinated contrast agent (e.g., a diagnostically effective compound), which is basically the same as the particle of example 14 in the

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specification. Thus, it is unclear what specifically applicant is asserting that Tsuru is missing as compared to the claimed invention.

Applicant asserts that Unger is no longer applicable because the claims have been amended to remove the term vesicle.

This is not found persuasive because Unger clearly defines the term vesicles in the patent to include "porous particles" etc., as set forth in the present claims, see column 6 and 7, especially, column 7, lines 7-10. The vesicles disclosed by Unger are within the scope of the particles, e.g., at least, the porous particles, as claimed. It is noted that the terms "vesicles" and "particles" are used somewhat interchangeably in the art, whereas, a clear delineation between these two terms does not exist.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38 and 4-6 rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,585,112) in view of Tsuru (5,055,307), for the reasons set forth in the office action mailed 4/21/2004.

Applicant again asserts that Unger is no longer applicable because the claims have been amended to remove the term vesicle.

This is not found persuasive because Unger clearly defines the term vesicles in the patent to include "porous particles" etc., as set forth in the present claims, see column 6 and 7, especially, column 7, lines 7-10. The vesicles disclosed by Unger are within the scope of the particles, e.g., at least, the porous particles, as claimed. It is noted that the terms "vesicles" and "particles" are used somewhat interchangeably in the art, whereas, a clear delineation between these two terms does not exist.

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Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael G. Hartley
Primary Examiner
Art Unit 1616

10/28/2004